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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,388	07/20/2001	Lawrence L. Kunz	295.003US5	1690

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,388	KUNZ ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on th cover sheet with the correspond nce address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/16/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-47 and 49-55* is/are pending in the application.

4a) Of the above claim(s) *21-47 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *50-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Restriction Requirement mailed on October 2, 2003 has been vacated as applicant canceled several claims restricted, in favor of the following office action.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-47 and 49 are drawn to a therapeutic method, classified in class 514, subclass 2+.

II. Claims 50-55 are drawn to method of reducing restenosis, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I and II are patentably distinct because the methods have different end points and method steps. For example, the method of Invention I is directed to treating procedural vascular trauma and the method of Invention II is directed to reducing restenosis.

Several of the inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the

invention of one group, would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

3. During a telephone conversation with Ms. Ann Chen for Kathy Chin on January 16, 2004, a provisional election was made without traverse to prosecute the Invention of Group II, Claims 50-55. Affirmation of this election must be made by applicant in responding to this Office action. Claims 21-47 and 49 are withdrawn from further consideration by the examiner, 37 CFR 1.142 (b), as being drawn to a non-elected invention.

4. The Preliminary Amendments filed on July 20, 2001 and January 13, 2004 has been received and entered.

Claim Disposition

5. Claims 1-20 and 48 have been canceled. Claims 50-55 have been added. Claims 21-47 and 49-55 are pending. Claims 50-55 are under examination.

Specification

6. The specification is objected to because of the following informalities:

The specification is objected to because page 1 does not accurately report the continuity data, as application number 09/470,662 is now patent number 6,268,390.

Correction of all of the above is required.

Oath/Declaration

7. It is noted that applicant filed a petition on 37 CFR 1.48(b) to correct inventorship, however, applicant did not file a new Oath/Declaration reflecting the changes made.

Correction is required.

Information Disclosure Statement

8. The information disclosure statement filed on 3/12/03 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed on the information disclosure statement that are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through the following items on the information disclosure statement: foreign documents: EP 0588518 to WO 95/03795, EP 0260066 to WO 94/25020, WO 94/28721 and all non-patented

literature except for references by : Akselband et al.; Graham et al.; Gregory et al.; Meiser et al.; Morris et al.; Morris; Nakano and Garg et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 50-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for the full scope of the claims. The specification is enabled for a method to reduce restenosis, however, is not fully enabled for any or all therapeutic agent that inhibits vascular smooth muscle cell migration as claimed, see for example claim 50. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Factors to be considered when determining

whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue including but not limited to:

(a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

I. Quantity of Experimentation Necessary:

The specification on page 4 asserts that the invention provides new therapeutic methods and therapeutic conjugates for inhibiting vascular smooth muscle cells in a mammalian host. The specification provides specific examples of therapeutic agents such as taxol analogs (i.e. taxotere) among others listed on pages 5+ (see for example pages 5-10). However, the claims are directed to "a method for reducing restenosis following vascular surgical procedure comprising administering locally a human biocompatible, non-biodegradable sustained release dosage form comprising a cytostatic amount of a free, non-binding partner associated therapeutic agent..." which broadly reads on any therapeutic agent. One of skill in the art would have to engage in undue experimentation to determine if all therapeutic agents that suppresses or inhibits vascular smooth muscle cell migration, does not exhibit substantial cytotoxicity and does not substantially inhibit protein synthesis and is a free non-binding partner associated therapeutic agent absent guidance/direction.

II. Amount of direction or guidance presented:

The amount of direction or guidance presented in the specification to be able to practice the claimed invention is inadequate based on the absence of exemplification of all the compounds that are considered to be a therapeutic agent. Therefore, the claimed invention cannot be practiced commensurate in scope with the claims.

III. Presence or absence of working examples/ Nature of the Invention:

The working examples provided do not rectify the problem of breath in the claims, that is not supported by the instant specification, as the unspecified amount of therapeutic agents having the effect as claimed is not supported by the disclosure. Therefore, the specification does not disclose methods for using the claimed invention that bears a reasonable correlation to the entire scope of the application disclosure, which is thus, not enabling.

IV. State of the prior art and Relative skill of those in the art:

The claimed invention is directed to a method to reduce restenosis and the metes and bounds of the claims are undefined as the claim encompasses an unlimited amount of therapeutic agents not disclosed or supported. It is known in the prior art that heparin suppresses smooth muscle cell proliferation and it is disclosed in the instant specification that heparin has a short pharmacological half life thus problematic, yet this is encompassed in the broad claim language of "a free... therapeutic agent". Therefore, the specification at the time the application was filed, would not have taught one skilled in the art how to make and or use the full scope of the claimed invention without undue experimentation.

V. Predictability or unpredictability of the art/Breath of the claims:

The specification on pages 2+ provides several examples of compounds that have adverse effects thus would not be desirable to practice the claimed method, however, these compounds are included in the breath of claim 50. This renders the invention as unpredictable.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 50-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and the dependent claims hereto are indefinite because the claim recites "a free, non-binding partner associated therapeutic agent" and it is unclear what is "an associated therapeutic agent. It is noted that a discussion is provided in the instant specification that indicates that a free non-binding partner is one that is not bound/conjugated to another partner, however, there is no indicia as to the "associated therapeutic agent" as an association implies a relationship and free implies no relationship.

Claim 51 lacks antecedent basis for the recitation of "therapeutic agent" when the independent claim recites "a free non-binding partner associated therapeutic agent".

Claim 55 is indefinite because the claim recites "wherein the locally administering occurs during or after the vascular procedure" and the independent claim recites "a method to reduce restenosis following a vascular surgical procedure", thus it appears that "after" is the only time the condition will occur, thus how can it be reduced "during", when it only occurs following the procedure? This appears to be a prevention rather than a reduction step.

Conclusion

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (571) 272-0957. The examiner can normally be reached on Monday-Friday from 9:00 am to 6:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (571) 272-0951.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER